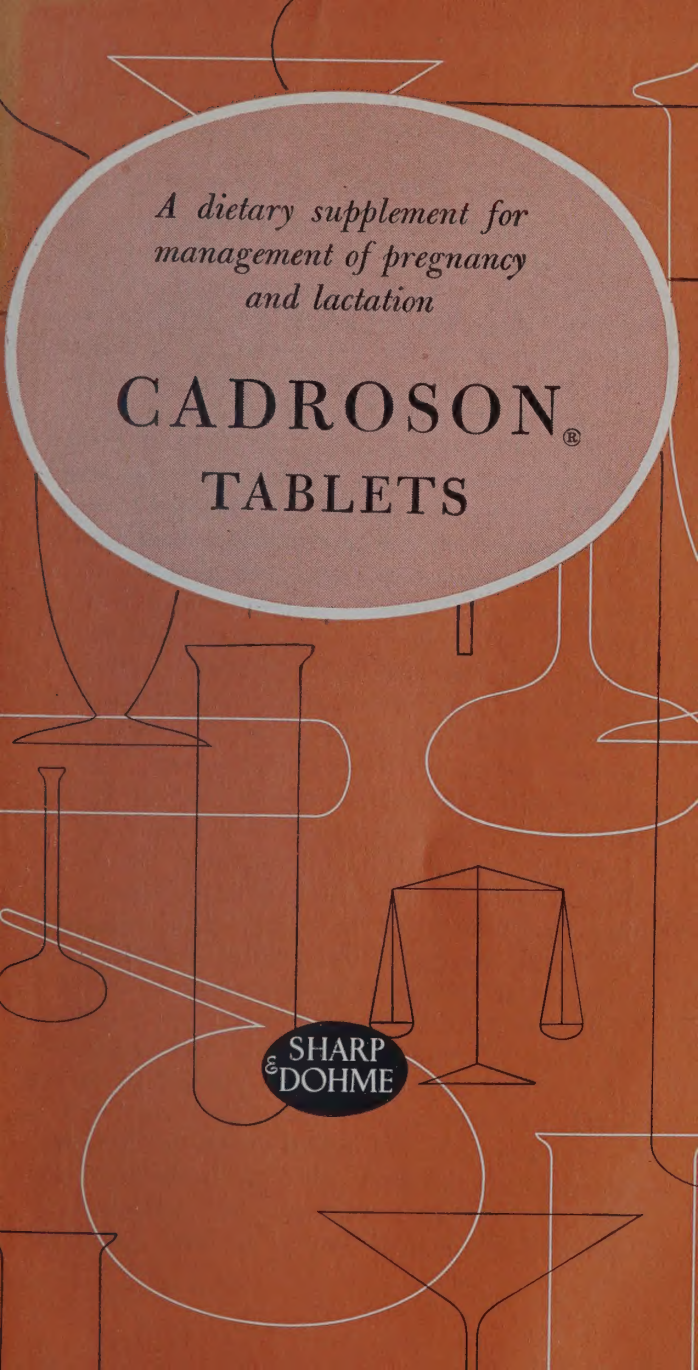
A dietary supplement for management of pregnancy and lactation

CADROSON®
TABLETS



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It is especially important that adequate quantities of calcium, phosphorus, iron, and vitamin D be readily available in assimilable form to pregnant and lactating patients. The dual requirements of mother and child can be satisfied by special dietetic management, but negative calcium and phosphorus balances occur not uncommonly during pregnancy[1, 2, 3] and lactation.[4] Negative iron balances have been noted also, and several investigators have reported iron retentions below the estimated fetal demand.[5, 6] Moreover, hypochromic anemia often is encountered during pregnancy and lactation. The advantage of administering supplemental quantities of vitamin D during pregnancy and lactation is well recognized in that it prevents the depletion of maternal resources, and the development of rickets and dental caries in the infant is less likely to occur.

The prevalence of dental caries among obstetric patients has been observed with great frequency. Calcium, phosphorus, and vitamin D all are important with respect to their favorable effect on tooth structure and their influence in the prevention of dental caries. Fluorine in amounts contained in bone meal has been reported also to exert a favorable effect with respect to the prevention of dental caries.[7, 8] Certain symptoms often encountered during pregnancy were observed to occur well below the anticipated incidence when bone meal containing fluorine was administered.[9]

In view of these related findings the Medical Research Division of Sharp & Dohme has developed 'Cadroson' Tablets, designed to provide dietary supplements considered to be of importance in the nutrition of obstetric patients and certain individuals prone to develop dental caries. Each **six** tablets contain:

Calcium	1.5	Gm.
Phosphorus	0.75	Gm.
Fluorine..not more than	0.5	mg.
Iron	15.0	mg.
Vitamin D.....	1,000	U.S.P. units

These amounts represent at least the average minimal daily requirement of each of the constituents, with the exception of fluorine for which no minimal requirement has been established.

Clinical Indications and Dosage

'Cadroson' Tablets are indicated as a dietary supplement in the management of pregnant and lactating women, and for the prophylaxis and management of dental caries. The average dose for adults and children above 12 years of age is one to two tablets three times a day, for children from 3 to 12 years of age in proportion.

Calcium-Phosphorus-Fluorine

The minimal daily requirement of calcium or phosphorus for a child or an adult has been established as 0.75 Gm. The ratio of calcium to phosphorus in 'Cadroson' Tablets is the same as that found in bone tissue (approximately 2.2 to 1).[10]

In a review article by Burke and Stuart[11] it is stated that "it is an accepted fact that calcium and phosphorus requirements are considerably increased during pregnancy, if the maternal organism's own stores are to be maintained and fetal needs met."

The relationship of fluorine to dental caries has become the subject of considerable recent investigation.[12-16] Sufficient evidence has been accumulated to conclude that dental caries is less prevalent among children who have used water containing fluorine from infancy. In communities where the drinking water does not contain fluorine in a quantity equal to 1 part per million, supplementation of the diet with this element may be desirable.

The fluorine in 'Cadroson' Tablets is approximately equal in amount to that contained in bone meal derived from selected beef bone. The administration of fluorine in the form of a preparation such as 'Cadroson' Tablets has the definite advantage of controlling the concentration of this element in the diet and thus facilitating administration of an optimal dosage.

Controlled studies carried out by Strean and Beaudet[17] indicated that in children who do not receive fluorine in drinking water or food, an average increase in caries incidence of from 40 to 65 per cent may be expected in six to eight months. This incidence of dental caries may be decreased markedly by the ingestion of fluorine and, furthermore, the efficacy of the latter appears to be enhanced by the addition of certain vitamins.

Branson[8] has pointed out that when therapy involves the ingestion of fluorine, calcium should be included as a balancing factor. The administration of bone meal together with vitamins A and D to pregnant women was found by Martin[9] to have a decidedly beneficial effect. Dental neuralgia did not occur, nor were there symptoms of aching or cramps in the legs. Dental caries was well below that expected following the usual unprotected pregnancy.

Nine patients with a previous history of high incidence of caries were given bone flour capsules.[7] After nine months of treatment it was observed that there was almost no advance in dental caries, and the author stated: "It seems very likely that the significant feature in the treatment is the fluorine content of the bone flour."

Iron

The normal adult requires a minimum of 10 mg. of iron daily in order to maintain the level of circulating hemoglobin within normal limits, and this is increased to 15 mg. during pregnancy and lactation.[18] Adair and his associates[19] have stated: "There is an increased need for iron in pregnancy to take care of the increased blood volume and for the fetal demands for its own body development and also as a reserve for postnatal growth." The occurrence of hypochromic microcytic anemia may be precipitated in the presence of inadequate iron

ingestion or low iron retention. Labate[20] observed that anemia was a frequent complication during pregnancy, and he noted, further, that the development of anemia was possible even though an adequate diet was supplied.

Vitamin D

The recommended daily allowance of this vitamin in pregnancy and lactation has been estimated to be from 400 to 800 U.S.P. units. It is known that this vitamin assists in the regulation of calcium and phosphorus metabolism with respect to the retention of these minerals in the body, their concentration in the blood, and their deposition in bony structure.[21, 22] The role of vitamin D in the formation of tooth structure and the prevention of dental caries has been studied by Mellanby and Coumoulos[23] who concluded that the teeth of the offspring are influenced by the diet of the mother during pregnancy. Vitamin D deficient diets resulted in late eruptions of the deciduous teeth and poor calcification. The permanent teeth also were affected adversely. Moreover, it has been demonstrated that vitamin D is excreted in human milk, and thus its antirachitic properties may be conveyed to the child if adequate quantities are administered to the lactating mother. In order to avoid undue maternal loss of calcium, phosphorus, and vitamin D the administration of extradietary quantities of these substances should be continued throughout the period of lactation.

Precautions

In areas in which the fluorine content of the water is known to be high, the recommended daily dosage of 'Cadroson' Tablets should not be exceeded except at the discretion of the physician.

How Supplied

'Cadroson' Tablets are supplied in bottles of 100 and 1,000.

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